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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/512,926	02/25/2000	Fred S. Lamb	P-1057	6913

7590

01/29/2003

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Applicati n N .

09/512,926

Applicant(s)

LAMB, FRED S.

Examiner

Jennifer Kim

Art Unit

1617

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-11,13 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) 14-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-11,13 and 22-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Applicant's petition filed December 10, 2002 to remove the finality has been treated as a request for reconsideration.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

The amendment filed on February 12, 2002 have been received and entered into the application. New claims 22-24 have been added. Claims 2, 5 and 12 have been cancelled in view of Applicants' request.

Applicant's arguments with respect to claims 1, 3, 4, 6-11 and 13 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C.

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122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 4, 6-10, 13, 23 and 24 is rejected under 35 U.S.C. 102(e) as being anticipated by Grainger et al.(U.S.Patent No. 6197789B1).

With regard to claims 13 and 24, Grainger et al. on column 3, lines 16-33, teach Applicant's active agent is orally administered to a mouse. Accordingly, Grainger et al. teach same active agent, and same method of administration as set forth by Applicants' claim 24, therefore Applicant's mechanism of action of affecting CLC3 receptors by administration of the same active agent would be inherent of cited reference.

With regard to claims 4 and 6-10, Grainger et al. on abstract, column4 lines 7-16, column 5, line 65 through column 6, line 30, column 7, lines 15-33, column 8, lines 11-20, column 10 lines 51-57, column 15, line 54, column 18, lines 34-44, column 24, lines 47-50, and column 25, lines 4-8, teach that Applicant's active agent is useful on vascular smooth muscle cells to inhibit the pathological activity of the smooth muscle cells, and to inhibit the activation of endothelial cells associated with vascular surgery, diabetes, hypertension, and coronary artery blockage. Applicant's recitation of the expression of the negative effects associated with vascular smooth muscle endothelium damage would be inherently encompassed by cited reference.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3, 11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grainger et al. (U.S. Patent No. 6,197,789 B1).

With regard to claims 1 and 3, Grainger et al. on column 3, lines 16-55, teach Applicant's active agent was exemplified to illustrate the inhibition of the pathological activity of these smooth muscle cells, by inhibiting the activation of endothelial cells which decreased a lesion formation or development and increase plaque stability in the transgenic mouse. The difference between above reference and Applicant's claimed invention is to employ Applicant's active agent to reduce the sensitivity of endothelially-compromised vascular smooth muscle in a patient. However, a skilled artisan would be motivated to employ Applicant's active agent to reduce or inhibit any activation of endothelium since the active agent is capable of inhibiting any activation of endothelial cells in endothelially-compromised atherosclerotic patient (transgenic mouse).

With regard to claim 11, Grainger et al. on abstract, column 4 lines 7-16, column 5, line 65 through column 6, line 30, column 7, lines 15-33, column 8, lines 11-20, column 10 lines 51-57, column 15, line 54, column 18, lines 34-44, column 24, lines 47-50, and column 25, lines 4-8, teach that Applicant's active agent is useful on vascular smooth muscle cells to inhibit the

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pathological activity of the smooth muscle cells, and to inhibit the activation of endothelial cells associated with vascular surgery, diabetes, hypertension, and coronary artery blockage.

The difference between above reference Applicant's claimed invention is further comprising the agents set forth in claim 11. However, a skilled artisan would have been motivated to incorporate other agents similarly useful in treatment of diabetes, hypertension and coronary artery disease together with the active agents in Grainger et al. to achieve at least additive effect.

None of the claims are allowed.

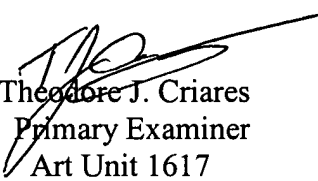
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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Theodore J. Criares  
Primary Examiner  
Art Unit 1617

jmk  
January 21, 2003